

Remarks

Claims 1 and 5-18 were pending in the subject application. By this Amendment, the applicants have amended claim 1 and added new claim 19. Support for the amendment to claim 1 and for new claim 19 can be found throughout the specification and the claims as originally filed including at, for example, page 5, fourth paragraph. No new matter has been added by these amendments. Accordingly, claims 1 and 5-19 are before the Examiner for consideration.

The amendment to claim 1 and the addition of claim 19 have been done in an effort to lend greater clarity to the claimed subject matter and to expedite prosecution. The amendments should not be taken to indicate the applicants' agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

Initially, the Office Action states that the syntax of claim 1 could be improved by amending the claim. By this Amendment, the applicants have amended claim 1 as suggested by the Examiner. The applicants appreciate the Examiner's helpful suggestion.

Claims 1 and 5-18 have been rejected under 35 U.S.C. 112, first paragraph. The applicants respectfully traverse this ground for rejection to the extent that it might be applied to the claims now presented for examination.

Please note that the applicants have amended claim 1 (and, by definition, the claims that depend from claim 1) to recite the treatment of sunburn and skin aging. The Office Action acknowledges at page 3 that the specification is enabling for the treatment of sunburn and skin aging. Thus, the applicants respectfully request the withdrawal of this rejection with respect to claim 1, and the claims that depend from claim 1.

With regard to new claim 19, it is important to bear in mind that for an invention to be enabled under the first paragraph of §112, the specification need only teach a person of ordinary skill in the art "how to make" and "how to use" the invention. See, e.g., *In re Angstadt*, 537 F.2d 498, 190 USPQ 214 (CCPA 1976).

Claim 19 recites the treatment of a specific condition (inflammation associated with damage induced by UV-radiation) wherein the treatment proceeds via a specific mechanism (i.e. by inducing the NER pathway). The identification of this mechanism, combined with the other

detailed teachings in the subject application, provide ample basis for the skilled artisan to make and use the claimed invention, as that invention is narrowly and specifically defined in new claim 19.

The examples provided by the applicants in the specification provide sufficient guidance for the skilled artisan to practice the amended and new claims without undue experimentation. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

Claims 1, 5-11, 13, 15 and 16 have been rejected under 35 U.S.C. 102(b) as being anticipated by Osaki *et al.* (J. Immunol., Vol. 160, p. 1742-1749). The applicants respectfully traverse this ground for rejection to the extent that it might be applied to the claims now presented for examination.

The applicants have amended claim 1 (and, by definition, the claims that depend from claim 1) herein in order to clarify the subject matter of the instant invention. In particular, claim 1 has been amended to recite a method of treating sunburn or skin aging. New claim 19 is also drawn to a very specific, unique treatment.

It is a basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra*; *Kalman [v. Kimberly-Clarke]*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

The Osaki *et al.* reference focuses on treatment of a particular melanoma, including the observation of changes in tumor area in various experimental environments. In contrast, the subject invention is a method for treating specific skin disorders that are different from the

disease condition described in the Osaki *et al.* reference. The Osaki *et al.* reference does not disclose or suggest treating the conditions as now claimed by the current applicants.

Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. 102(b) based on the Osaki *et al.* reference.

Claim 14 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Osaki *et al.* The applicants respectfully traverse this ground for rejection because the cited reference does not disclose or suggest the applicants' advantageous method, as now claimed.

The shortcomings of the Osaki *et al.* reference with respect to the current invention have been discussed above. Given the important differences in the underlying teachings of the cited reference compared to the characteristics of the current invention, there would be no reason to modify the teachings of the Osaki *et al.* reference to arrive at the current invention.

It is well established in the patent law that the mere fact that the purported prior art could have been modified or applied in some manner to yield an applicant's invention does not make the modification or application obvious unless "there was an apparent reason to combine the known elements in the fashion claimed" by the applicant. *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_\_ (2007). Furthermore, an applicant's invention is not "proved obvious merely by demonstrating that each of its elements was, independently, known in the (purported) prior art." *Id.*

The Court of Customs and Patent Appeals was faced with an analogous situation in *In re Hayashibara and Sugimoto*, 188 USPQ 4 (CCPA 1975). The PTO Board of Appeals had affirmed a §103 rejection, and the CCPA reversed, stating:

Turning to the . . . rejection . . . for obviousness under 103, we agree with appellants that there is nothing in the reference which would lead those of ordinary skill in the art to employ [the substance] as appellants do in the product of claim 11. The reference does not teach [the substance] as possessing any of the characteristics or functions upon which appellants' claimed invention depends (emphasis added).

The cited reference does not disclose or suggest the subject matter of the applicants' claim 14. Nor would there be any reason for the skilled artisan to modify the teachings of the cited reference to arrive at the current invention. Accordingly, the applicants respectfully request reconsideration and withdrawal of the obviousness rejection under 35 U.S.C. §103 based on the Osaki *et al.* reference.

In view of the foregoing remarks and the amendments above, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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